

K 954625

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VI. Summary of Safety and Effectiveness Information

Trade name: Thrombolytic Assessment System Prothrombin Time Test Card (TAS PT Test Card)

Common Name: PT Test

Classification Name: systems for in vitro coagulation studies, automated or semiautomated instruments and associated reagents and controls used to perform a series of coagulation studies and coagulation factor assays (Class II. 21 C.F.R. 864.5425)

Predicate Device: The proposed TAS PT test card made with thromboplastin from human placenta is substantially equivalent to the marketed TAS PT test card made with rabbit brain thromboplastin (K882456).

Description of the Device: The TAS Prothrombin Time test card provides a one stage method which measures the clotting time of a sample after combining it with activator. This test consists of a single card that contains calcium chloride to initiate clotting in citrated blood samples, tissue thromboplastin as an activator, buffer, and stabilizers. Samples are tested by drawing venous or arterial blood into a sodium citrate tube and briefly mixing by gentle inversion. This allows the operator to control the start of the clotting reaction which requires recalcification. Because the sample is citrated, additional tests such as aPTT can be performed with the same sample. The test card has a magnetic stripe on the back which encodes lot specific information such as number, expiration date, and calibration factors specific to that lot. A room temperature test card is removed from the pouch and the card is passed through the instrument's stripe reader to program the instrument to run a PT. The instrument then requests patient and sample information and instructs the operator to insert a PT test card. The card is quickly warmed and the operator is prompted to add a sample drop of blood to the card sample well. The sample is drawn into the card and rehydrates the PT reagent which recalcifies the sample and begins the clotting reaction. As the reaction proceeds and clotting begins, the movement of the particles decreases, and the instrument signals the clotting time. Low levels of extrinsic clotting factors will cause prolongation of clotting time.

Intended Use: The new TAS PT test card, as the existing marketed TAS PT test card made with rabbit brain thromboplastin, is intended to be used with the TAS Analyzer to determine the prothrombin time in citrated whole blood or plasma.